No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICALS INDUSTRIES, LTD.,

Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE*, MASSACHUSETTS BIOTECHNOLOGY COUNCIL ("MASSBIO"), IN SUPPORT OF PETITIONER

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INTEREST OF THE MASSACHUSETTS BIOTECHNOLOGY COUNCIL ("MASSBIO")

Founded in 1985, the Massachusetts Biotechnology Council ("MassBio")[1] is a nonprofit association of more than 1,000 biotechnology companies, academic institutions, disease foundations, and other organizations involved in life sciences and healthcare, principally all based or active in the Commonwealth of Massachusetts. Of the more than 600 MassBio members that are life sciences companies, more than 88% have less than 250 employees worldwide, and 74% have less than 50. These small and midsize biotechnology companies depend on strong patent rights and collaborations with other parties to maintain their ability to research, develop, and commercialize breakthrough therapies and cures, and to ensure that patients around the world have affordable access to those new treatments.

MassBio opposes policies and laws that threaten patient access, limit innovation, or hurt the Massachusetts life sciences industry's competitiveness in the global economy. Moreover, because of the already numerous challenges faced by small and midsize biotechnology companies and the heavy reliance of

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[1] MassBio has no financial interest in any party or the outcome of this case. This brief was neither authored nor paid for, in whole or in part, by any party. Counsel of record received timely notice of the intent to file the brief under Supreme Court Rule 37. Both Petitioner and Respondents have consented to the filing of this brief through blanket consent letters filed with the Clerk's Office on March 13, 2018 and March 19, 2018, respectively.

these innovators on patent protection, MassBio is particularly concerned with the uncertainty and chilling effect established by the Federal Circuit's decision below regarding the types of transactions that may trigger the "on-sale" bar. MassBio believes that its industry experience and perspective will provide useful information for the Court's consideration of the petition.

SUMMARY OF ARGUMENT

This case concerns a question of critical importance to the biotechnology and pharmaceutical industries: whether the public disclosure of the mere existence of confidential and often necessary pre-marketing activities can be used to invalidate an innovator's patent. The Petition requests that this Court clarify the scope of what activities qualify as prior art under the "on-sale bar" reflected in the amended language of § 102(a)(1) of the Leahy-Smith America Invents Act (AIA). Because of the significant uncertainty created by the Federal Circuit's decision below regarding the on-sale bar, and the exceptional importance of the issue to the biotechnology community, the Court should grant the petition for a writ of certiorari.

The Federal Circuit's decision below raises serious questions concerning the application of the on-sale bar to confidential pre-marketing activities that are often necessary to bring life-saving medicines to market. Notwithstanding statements by the panel and Judge O'Malley's later concurrence in the denial

of rehearing *en banc* characterizing the ruling as narrowly tailored to the particular agreement at issue, the decision in fact contains broad, sweeping language concerning public disclosure. The Federal Circuit's unusual analysis regarding the meaning of "on sale" has created murky waters for patentees in the post-AIA world. For example, the decision below is unclear as to whether the pre-AIA analytical framework for determining what constitutes a commercial sale for purposes of pre-AIA § 102(b) extends to the amended language of AIA § 102(a)(1). As a result, it remains uncertain whether public disclosure of the mere *existence* of a sale of an invention would qualify, on its own, as an invalidating act under the AIA.

This uncertainty is particularly harmful to the members of the biotechnology industry, many of whom are members of *Amicus*. In particular, the Federal Circuit's decision disproportionately affects small and midsize companies that depend on valid patents and pre-marketing collaborations in order to bring new drugs to market. The decision below has created a cloud of uncertainty over the risks associated with pre-marketing transactions and an overall chilling effect on innovation and collaboration in the biotechnology space. Absent clarification from this Court, the companies that research and develop the majority of new, approved drugs in the United States will be forced to either forgo their patent rights in order to fund the development of life-saving therapies or face the prospect of never making it to market at all.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION CREATES SIGNIFICANT UNCERTAINTY CONCERNING THE SCOPE OF THE ON-SALE BAR UNDER AIA § 102(a)(1).

The decision below raises serious questions as to what activities may trigger the on-sale bar in the post-AIA world. In particular, the Federal Circuit's repeated and extensive focus on the public disclosure of the mere *existence* of a sale or offer for sale makes it unclear whether such disclosure, on its own, qualifies as an invalidating act under § 102(a)(1).

On the one hand, the Federal Circuit's decision included an analysis of several facts relating to the transaction between Helsinn and MGI. *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1361-62, 1369 (Fed. Cir. 2017). The Federal Circuit described the agreement between Helsinn and MGI as "bear[ing] all the hallmarks of a commercial contract for sale," noting in particular the structure of the agreement, the supply obligations, the methods of payment and delivery, and the applicable termination procedures in the event of unfavorable clinical trial results or a failure to obtain FDA approval. *Id.* at 1365, 1362. The court also emphasized that "[a]ll of the above information about the transaction was publicly disclosed," except for the specific price terms and the exact (claimed) 0.25 mg dosage of the product. *Id.* at 1362.

Judge O'Malley pointed to this analysis in her concurrence in support of the denial of *en banc* review

as evidence that the Federal Circuit's decision had properly considered a number of factors in deciding that the particular agreement at issue triggered the on-sale bar. *See Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, App. Nos. 2016-1284, -1787 (Fed. Cir. Jan. 16, 2018) (denying *en banc*) (O'Malley, J., concurring), slip op. at 2-3. The problem, however, is that the decision below considered these factors as part of the *pre*-AIA framework to find that the agreement constituted a commercial sale or offer for sale for purposes of *pre*-AIA § 102(b). *See Helsinn*, 855 F.3d at 1367 (discussing these facts as part of the analysis for the three pre-AIA patents at issue). When the Federal Circuit finally turned to address the on-sale bar *post*-AIA under the amended language of § 102(a)(1), however, the court appeared to create a new rule.

The parties had argued below at great length over whether the amended language of § 102(a)(1) changed the meaning of the on-sale bar. Petitioner argued that the amendment and the express legislative intent behind the amendment "was to eliminate secret sales as prior art and to require that the sale *make the claimed invention available to the public*" in order to be invalidating. Pet. at 7 (citations omitted) (emphasis added). *See also* 157 CONG. REC. S1370 (daily ed. Mar. 8, 2011) (statement of Senator Kyl) ("Moreover, the fact that the clause 'or otherwise available to the public' is set off from its preceding clauses by a comma confirms that it applies to both 'public use' and 'on sale.' . . . Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is

predicated."). As such, Petitioner argued that under the AIA's amended § 102(a)(1), the on-sale bar should not apply where the claimed invention—in this case, the precise formulation of palonosetron—was not made available to the public or placed into the public domain. Respondents, on the other hand, argued below that the preservation of the term "on sale" within the language of § 102(a)(1) indicated that Congress did not change the meaning of the on-sale bar or disturb settled law. *See Helsinn*, 855 F.3d at 1356.

The Federal Circuit appeared at first to reject a broad resolution of the parties' dispute as to whether the AIA changed the meaning of the on-sale bar. Stating that it was "declin[ing] the invitation by the parties to decide this case more broadly than necessary," it then discussed its prior jurisprudence, applying the previous statutory language of pre-AIA § 102(b), and found that there was no indication from the floor statements that Congress intended to overrule those prior cases. *See, e.g.*, *Helsinn*, 855 F.3d at 1370-71. The court further cautioned that interpreting the on-sale bar to require that the sale publicly disclose the specific claimed invention "would work a foundational change in the theory of the statutory on-sale bar."[2]

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[2] Notably, the Federal Circuit's reluctance to interpret the amended language of § 102(a)(1) as changing the law ignores that statutory upheaval is precisely what Congress intended by enacting the AIA. *See generally* John Villasenor, *The Comprehensive Patent Reform of 2011: Navigating the Leahy-Smith America Invents Act*, Policy Brief No. 184, Brookings Institution (Sept. 2011) (the AIA "constitutes the most significant overhaul of the American patent system in decades"); 157 CONG. REC. S1362 (daily ed. Mar. 8, 2011) (statement of Senator

Yet, despite its expressed reticence, the Federal Circuit went further and found that "[i]n stating that *the invention must be available to the public* [Congress] evidently meant that *the public sale itself* would put the patented product in the hands of the public." *Id.* at 1371 (emphasis added).[3] Thus, despite stating that it would not decide whether the AIA changed the meaning of the on-sale bar, as was argued by the parties and *amici* below, the Federal Circuit arrived at its own, new interpretation of the AIA based on certain floor statements of Congress and categorically held: "We conclude that, *after* the AIA, if *the existence of the sale is public*, the details of the invention need not be publicly disclosed in the terms of sale" in order for the sale to be invalidating. *Id.* at 1368, 1371. The court then held that "both the pre-AIA and AIA on-sale bars apply" to the agreement in this case. *Id.* at 1371. *See also id.* at 1369 (distinguishing prior cases and legislative intent because "[h]ere, the existence of the sale—*i.e.*, the Supply and Purchase Agreement between Helsinn and MGI—was publicly announced in MGI's 8-K filing with the SEC").

Leahy) (the AIA provides "the first meaningful, comprehensive reforms to the nation's patent system in nearly 60 years"); 157 CONG. REC. S1495 (daily ed. Mar. 9, 2011); 157 CONG. REC. H4429 (daily ed. June 22, 2011).

[3] The Federal Circuit similarly conflated cases concerning the "public sale" of an invention (whereby the *invention* is placed in the public domain) with instances where the invention is kept secret, but the existence of an otherwise confidential or private sale regarding the invention "is made public." *Helsinn*, 855 F.3d at 1369-70 (citing *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829)).

The Federal Circuit's analysis, on the one hand, of multiple factors regarding the pre-AIA on-sale bar and its broad decree, on the other hand, concerning the sole factor of the mere *existence* of a sale after the AIA thus raises serious questions as to the application of the on-sale bar going forward. It is unclear based on the decision whether the pre-AIA framework—where public disclosure "is just one of several factors for determining whether the transaction rises to the level of a commercial sale"—would control the analysis, or whether, as suggested by the Federal Circuit's *sua sponte* interpretation of Congress's intent, "*the public sale itself* would put the patented product in the hands of the public" *after* the AIA. *Compare Helsinn*, App. Nos. 2016-1284, -1787 (O'Malley, J., concurring), slip op. at 3, *with Helsinn*, 855 F.3d at 1371 (emphasis added).

Judge O'Malley attempted to soften the Federal Circuit's language in her later concurrence in support of the court's denial of *en banc* review. *See Helsinn*, App. Nos. 2016-1284, -1787 (O'Malley, J., concurring), slip op. at 2-4. Citing back to the Federal Circuit's interpretation of the pre-AIA on-sale bar in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), Judge O'Malley clarified that the "single factor" of the confidentiality of the sale "is not dispositive of the analysis." *Id.* at 3. Judge O'Malley also stated that the Federal Circuit's decision had been limited, and that all it held "was that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." *Id.* (emphasis in original). As support, Judge O'Malley noted that "Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI" and further

pointed to the Federal Circuit's discussion of other information that had been disclosed by the 8-K SEC filing, including that a partially-redacted copy of the agreement itself had been included with the filing, that the agreement described the claimed drug formulation in detail, and that the agreement expressly contemplated the passage of title. *Id.* (citing *Helsinn*, 855 F.3d at 1361, 1364, 1366).

Unfortunately, Judge O'Malley's reliance on the Federal Circuit's consideration of the additional information contained in the agreement that was disclosed by the 8-K filing is directly contrary to the Federal Circuit's own conclusion that, in the post-AIA world, "if the existence of the sale is public, *the details of the invention need not be publicly disclosed in the terms of sale*" in order for the sale to trigger the on-sale bar. *Helsinn*, 855 F.3d at 1368, 1371 (emphasis added). Thus, the very information that Judge O'Malley asserted was relevant to the case and "weighed strongly in favor of finding that the on-sale bar was triggered" is precisely what the Federal Circuit held is no longer necessary post-AIA if the existence of the sale itself is made public.

Accordingly, because of the Federal Circuit's unusual emphasis on the public disclosure of the existence of a sale, rather than the disclosure of the claimed invention by the sale, the scope of the on-sale bar after the AIA has been left open and indefinite. This Court should thus grant review to clarify the applicability of the on-sale bar in view of the amended language of § 102(a)(1).

II. CLARIFICATION OF THE FEDERAL CIRCUIT'S DECISION IS VITAL TO INNOVATION AND COLLABORATION IN THE BIOTECHNOLOGY SPACE.

The need for clarification concerning the scope of the AIA on-sale bar is of critical importance to industries where pre-marketing transactions and collaboration are essential for success. The uncertainty created by the Federal Circuit's decision has a particular chilling effect on innovation and collaboration within the biotechnology industry.

Biotechnology largely remains a small company industry, and the cost of biotech development is incredibly high. On average, it takes 10 to 15 years and approximately $2.6 billion to successfully bring a new drug to market—more than double the cost during the 1990's and early 2000's. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D costs*, 47 J. HEALTH ECON. 20-33 (2016). Because many biotechnology companies operate without revenue, these costs represent significant challenges to companies seeking market entry. *See* Lisa Eckelbecker, *Biotech Startups Face Bigger Funding Challenges Than Other Industries*, TELEGRAM & GAZETTE, June 19, 2016, http://www.telegram.com/news/20160619/biotech-startups-face-bigger-funding-challenges-than-other-industries (noting the struggles of biotech companies in securing funding and one company's solution to "develop compounds up to the point that he could license something to a pharmaceutical company for the preclinical studies that lead to human testing").

Notwithstanding the funding challenges, however, small and midsize biotechnology companies have proven

to be leaders in researching and developing breakthrough therapies and cures. *See* HBM Partners, *Trends in US New Drug Approvals* (Jan. 2018) at 1 ("As in previous years, the majority (76%) of NMEs approved in 2017 originated from smaller or mid-sized biopharma companies, *i.e.* companies outside of the 30 largest biopharma firms."). Because "these smaller companies often out-license their drug candidates or were acquired themselves before approval, the number of approvals under their name" —18 in 2017—actually "understates their important contribution to pharmaceutical innovation." *Id.* at 10.

As an example, Massachusetts is the nation's leading state for biotechnology innovation, with over 34,000 jobs classified as Biotechnology Research and Development—more than any other state. *See* MassBio, *Industry Snapshot 2017*, at 3, http://files.massbio.org/file/MassBio-Industry-Snapshot-2017.pdf. However, of the over 600 member companies of *Amicus*, at least 88% have less than 250 employees worldwide, and 74% have less than 50. Many have no revenue. Yet, Massachusetts researchers are currently researching and developing products for patients with over 380 different medical indications, including various cancers, neurological conditions, immune disorders, Alzheimer's, and diabetes. *Id.* at 25. As of 2017, Massachusetts's biotechnology drug development pipeline made up roughly one-fifth of the total U.S. drug pipeline. *Id.* at 23.

Because of the high cost of drug development and the limited resources available to most small and midsize biotechnology companies, these companies tend to rely on business partners to support their

research and development. In the case of Helsinn, and many similarly-situated companies, entering into distribution or supply agreements with a partner is necessary to obtain sufficient upfront funding to advance pipeline products through clinical trials and to gain access to critical expertise that these small companies cannot, as a practical matter, develop themselves. *See Helsinn*, App. Nos. 2016-1284, -1787 (O'Malley, J., concurring), slip op. at 12. However, if a potential business partner is a public company and required to disclose the existence of such transactions, under the Federal Circuit's decision, such a disclosure (even without any meaningful disclosure of the underlying technology that is the subject of the transaction) could cost the innovating company its patent rights. This uncertainty about what actions trigger the "on-sale" bar puts biotechnology companies in an untenable situation to choose between ensuring patent protection for their inventions (often the most valuable business assets they own) or being able to develop and commercialize their products.

The Federal Circuit has previously held that, under pre-AIA § 102(b), "[t]here is no room in the statute and no principled reason raised by the parties or any of the amici to apply a different set of on-sale bar rules to inventors depending on whether their business model is to outsource manufacturing or to manufacture in-house." *Meds. Co.*, 827 F.3d at 1378-79. The court appeared to acknowledge then the danger of "penalizing a company for relying, by choice or by necessity, on the confidential services" of another company in assisting with the development of life-saving medicines. *Id.* The Federal Circuit's apparent expansion of the scope of the AIA's on-sale bar in this case walks

squarely into that danger and has created a chilling effect that disproportionately harms small and midsize biotechnology companies. This Court should thus accept this case for review in order to resolve the uncertainties created by the Federal Circuit's decision below.

CONCLUSION

For the foregoing reasons, *Amicus* respectfully requests that this Court grant the petition for a writ of certiorari.

Respectfully submitted,

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